Consolidated Health Informatics

Standards Adoption Recommendation

Text Based Reports

Index

Summary

Domain: Text Based Reports

Standards Adoption Recommendation:
Health Level Seven® (HL7®) CDA Release 1.0-2000

SCOPE
Identify standards and terminologies used to define the messaging architecture and syntax of clinical text documents

RECOMMENDATION
Health Level Seven® (HL7®) CDA Release 1.0-2000

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APPROVALS AND ACCREDITATIONS
HL7® is an ANSI-accredited Standards Developing Organization. This standard has been approved by full organizational ballot voting.

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HL7® sells hard and computer readable forms of the various standard versions, cost from $50 - $500 depending on specific standard and member status.

Part I – Team & Domain Scope Identification

Target Vocabulary Domain

Common name used to describe the clinical/medical domain or messaging standard requirement that has been examined.

Text-Based Reports

Describe the specific purpose/primary use of this standard in the federal health care sector (100 words or less)

Identify standards and terminologies used to define the messaging architecture and syntax of clinical text documents. Initially, all clinical documents types were considered as possible sub-domains. Additional sub-domains were further delineated from initial analysis of content of clinical document types, including section headings and data-types. The group reached consensus that inclusion of these sub-domains would result in scope that was much too broad to be completed in the short time frame and resources allocated. Document components and data domains contained in text-documents overlap broadly with areas already covered by other CHI groups.

Sub-domains *Identify/dissect the domain into sub-domains, if any. For each, indicate if standards recommendations are or are not included in the scope of this recommendation.*

Domain/Sub-domain	In-Scope (Y/N)
Text-Document structure and syntax	Y
Electronic Signature	Y
Document Section Headings	Y
Clinical Document Types/Titles	Y
Document Components and Data Domains	*N*
Clinical Signs and Symptoms	*N*
Vital Signs	*N*
Physical Exam Observations and Findings	*N*
Laboratory Findings	*N*
Diagnoses and Problems	*N*
Orders	*N*

Information Exchange Requirements (IERs) *Using the table at appendix A, list the IERs involved when using this vocabulary.*

Body of Health Services Knowledge
Care Management Information
Case Management Information
Customer Health Care Information

Population Member Health Data
Referral Information

Team Members *Team members' names and agency names with phone numbers.*

Name	Agency/Department
Dr. Viet Nguyen (co-leads)	**VA**
Linda Nugent (co-leads)	**VA**
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Dr. Howard Hays	HHS/IHS
Nancy Orvis	DoD
Dr. Timothy Mayhew	HHS/IHS
Alicia Bradford	CMS
Sandy Bailey	VA
Derek Wang	SSA
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Work Period *Dates work began/ended.*

Start	End
Oct 2003	Dec 2003

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

Health Level Seven® CDA Release 1.0-2000 and subsequent releases. (HL7® released ballot for CDA Release 2.0 on December 8, 2003. (It is anticipated that this new release will be ANSI-certified before the end of 2004.)

Ownership Structure *Describe who "owns" the standard, how it is managed and controlled.*

Headquartered in Ann Arbor, MI, Health Level Seven® (HL7®), is like most of the other SDOs in that it is a not-for-profit volunteer organization. Its members consist of providers, vendors, payers, consultants, government groups and others who have an interest in the development and advancement of clinical and administrative standards for healthcare. Like all ANSI-accredited SDOs, HL7® adheres to a strict and well-defined set of operating procedures that ensures consensus, openness and balance of interest. Health Level Seven® develops specifications; the most widely used being a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data. Members of Health Level Seven® are known collectively as the Working Group, which is organized into technical committees and special interest groups. The technical committees are directly responsible for the content of the Standards. Special interest groups serve as a test bed for exploring new areas that may need coverage in HL7®'s published standards.

Summary Basis for Recommendation *Summarize the team's basis for making the recommendation (300 words or less).*

The HL7® Clinical Document Architecture (CDA) is a standardized representation of clinical documents (such as reports of medical history and physical examination, progress notes and many others).

The CDA is part of HL7®'s Reference Information Model (RIM), which specifies the data objects and relationships between these objects involved in health care communication. The CDA Standard Version 1.0 has been published as an ANSI approved standard in November 2000.

The HL7® Clinical Document Architecture [CDA] is a framework for exchange of clinical documents. XML Document Type Definitions [DTDs] written for specific applications and environments can be mapped to the CDA. Using ISO standard 10744 can transform documents with their locally defined tags into documents carrying the industry-standard HL7® CDA markup. The CDA is based on a set of design principles that include keeping the barrier to entry low, while providing a migration path to

sophisticated electronic medical records for implementers and for the standard itself.

HL7® XML Version 3 messages are defined by XML document type definitions (DTDs), one for each type of message, such as clinical orders and results or patient registrations. The DTDs themselves are derived from portions of the HL7® RIM through a methodology that is sufficiently rigorous to permit precise formulations of vendor conformance and testing. As XML is applied to a widening number of problems in many industries, it will bring special benefits to HL7®. Instead of building specialized HL7® parsers from scratch, implementers can use the ubiquitous XML parsers adding validation constraints as required. There will be a broader group of trained people, minimizing recruiting difficulties for vendors and providers. And related specifications and tools, such as style sheets and XML-aware office suites will simplify the development of applications derived from the HL7® message flow. By leveraging the use of XML (Extensible Markup Language), the HL7® Reference Information Model (RIM) and coded vocabularies, the CDA makes documents both machine-readable—so they are easily parsed and processed electronically—and human-readable—so they can be easily retrieved and used by the people who need them. CDA documents can be displayed using XML-aware Web browsers or wireless applications such as cell phones or other hand-held devices.

The combination of clear definitions and interrelations of medical terms (as in LOINC® and SNOMED®) used to populate an HL7® standardized "message" or document using standardized syntax (eg, XML) will allow medical information to be transmitted to and retrieved from any telecommunication system connected to the World Wide Web. In turn, this achievement could enable a clinician to retrieve any patient's medical chart, laboratory and radiology reports, and other necessary information anywhere, anytime, given proper security, if we all use these same standards. Information represented in this format will allow manipulation of data to facilitate advanced functions, including record searches, patient-specific guidelines, outcomes research, or other functions.

CDA specification is richly expressive and flexible. Document-level, section-level and entry-level templates can be used to constrain the generic CDA specification. The Structured Documents Technical Committee of HL7®, which sponsors CDA development, is collaborating with other document groups such as the developers of the Continuity of Care Record (CCR) and the FDA to create templates for documents. This demonstrates a willingness and desire to promote the standard and accommodate the needs of users. Mechanisms for backwards and forwards compatibility with previous CDA releases are present. The independent platform allows different vendors to view documents. Adoption and implementation of the standard has begun in other countries.

Release Two of the CDA is currently out for ballot. Compared to the CDA, Release 1, the basic model of CDA, Release Two is essentially unchanged. A CDA document has a header and a body. The body contains nested structures (such as sections). These structures can be coded using standard vocabularies, and can contain CDA entries. The main evolutionary steps in CDA, Release Two are that both header and body are fully HL7® RIM-derived, and there is a much richer assortment of entries to

use within CDA structures. CDA, Release Two enables clinical content to be formally expressed to the extent that is it modeled in the RIM

The group endorses the approach the CDA uses for document titles. The CDA currently recommends the preferential use of LOINC® codes for document titles.

The General Services Administration, in coordination with the Office of Management and Budget is in the midst of developing a government-wide E-Authentication Policy. The key objective is to create a government-wide standard framework for assessing e-government electronic transaction authentication requirements.

The draft E-Authentication Policy was published in the Federal Register on July 11, 2003 for public comments. The Policy establishes a four level approach for authentication to ensure trustworthy electronic transactions and to fulfill Federal privacy and information security requirements. It also specifies a three step implementation process including: (1) conduct risk assessment in accordance with the guidance explained in Part II of the Government Paperwork Elimination Act and Section 2 of the proposed Policy; (2) determine the appropriate assurance level based upon the identified risks; and (3) deploy the corresponding technology solution based on the e-authentication technical guidance to be issued by the Department of Commerce's National Institute of Standards and Technology (NIST).

The workgroup considers the GSA/OMB E-Authentication Policy and the NIST FIPS Pub 199 as the defining documents for authentication control. Upon the release of the final E-Authentication Policy and the companion NIST technical guidance, the workgroup recommends that CHI reconvene a workgroup to review the guidelines and recommend adherence to risk assessment evaluation and application of appropriate security technology.

Conditional Recommendation *If this is a conditional recommendation, describe conditions upon which the recommendation is predicated.*

No conditional recommendations

Approvals & Accreditations

Indicate the status of various accreditations and approvals:

Approvals & Accreditations	Yes/Approved	Applied	Not Approved
Full SDO Ballot	Yes		
ANSI	Yes, ANSI-accredited SDO		

Options Considered *Inventory solution options considered and summarize the basis for not recommending the alternative(s). SNOMED must be specifically discussed.*

HL7® CDA (Clinical Document Architecture): *Selected*

HTML Hypertext Markup Language (HTML): *Not Selected*

- HTML is a specification of the W3C that provides markup of documents for display in a web browser. Computer-processible annotations reside within a multimedia document. Markup encodes a description of a document's storage layout and logical structure. There are no standard architecture statements for clinical documents. During 1999, HTML 4 was re-cast in XML and the resulting XHTML 1.0 became a W3C Recommendation in January 2000.

XML Extensible Markup Language (XML): *Not Selected*

- XML is a flexible and extensible messaging standard, also released by the World Wide Web Consortium. This specification supports the use data objects, document layout, validation of document structure and others. XML allows data to be presented in both human and machine-readable forms and is the basis for HL7's Clinical Document Architecture. However, XML stops short of prescribing standards for clinical documents.

Rich Text Format Rich Text Format (RTF): *Not Selected*

- RTF is a format that permits the viewing and editing of text and graphical documents across multiple operating system platforms. Applications are used to translate the document between different operating systems. This format supports ANSI, PC-8, Macintosh, or IBM PC character sets. This is a document display and format standard. It does not provide architecture for clinical documents.

Portable Document Architecture (PDA): *Not Selected*

- PDA is a format that permits the viewing and editing of text and graphical documents across multiple operating system platforms. Applications are used to translate the document between different operating systems. This format supports ANSI, PC-8, Macintosh, or IBM PC character sets. This a document display and format standard. It does not provide architecture for clinical documents

Clinical LOINC®: *Not Selected*

- In conjunction with HL7®, the Clinical LOINC® committee has developed a document title naming nomenclature based on a five-axis model. These axes include the kind of document (e.g. Clinical, administrative, consent), subject matter domain (e.g. internal medicine, physical therapy), type of service (e.g. procedure, consult, discharge summarization), author/role (e.g. physician, nurse, attending), and location (e.g. clinic, critical care unit, nursing home). Currently, over two-hundred codes for document titles exist. Recently, the Veterans Administration submitted an additional 150 titles for approval. Clinical LOINC® codes are also available for coding physical examination findings as well as specific findings of diagnostic procedures. Within the HL7® CDA architecture, the standard accommodates the clinical LOINC® document titles. At this point in time, Clinical LOINC® does not contain sections to documents as does the CDA.
- Currently, there are over 200 coded document titles, including codes for HIPAA

attachments. The use of coded document titles will improve document storage, retrieval and transmission within and across institutions.

Comité Européan de Normalisation (CEN): *Not Selected*

- CEN is the European Committee for Standardization. The CEN standard ENV 13606 is their standard for health informatics electronic healthcare record communication for the exchange of information. Recent analysis of the HL7® CDA release 2.0 level 1 specification shows that 13606 and CDA are semantically quite compatible (a CDA Document appears to be more or less equivalent to the 136066 Composition). Work done in the HL7® CDA Technical Committee indicates that HL7® members are interested in convergence of CDA and EHR specifications such as openEHR and 13606. A number of funded projects using the HL7® CDA are underway internationally, including Europe (Denmark, Finland, UK, Germany, etc); these could clearly benefit from access to a CDA-compatible specification based on EHR models. Efforts are in place to harmonize CEN 13606 with the HL7 ®CDA.

Abstract Syntax Notation One (ASN.1): *Not Selected*

- ASN.1 is a formal language for abstractly describing messages to be exchanged among an extensive range of applications involving the Internet, intelligent network, cellular phones, ground-to-air communications, electronic commerce, secure electronic services, interactive television, intelligent transportation systems, Voice Over IP and others. Due to its streamlined encoding rules, ASN.1 is also reliable and ideal for wireless broadband and other resource-constrained environments. Its extensibility facilitates communications between newer and older versions of applications. It does not provide an architecture for clinical documents.

SNOMED CT®: *Not Selected.*

- SNOMED CT®, a reference medical terminology, is not a document structure or document syntax. Yet, it does have a role to play in providing clear definitions and interrelations of medical terms that could be used to populate a standardized "message" or document using standardized syntax to allow medical information to be transmitted or exchanged.

Continuity of Care Record (CCR): *Not Selected*

- The CCR, or Continuity of Care Record, is a standard specification being developed jointly by ASTM International, the Massachusetts Medical Society (MMS), the Health Information Management and Systems Society (HIMSS), and the American Academy of Family Physicians (AAFP). It is intended to foster and improve continuity of patient care, to reduce medical errors, and to assure at least a minimum standard of health information transportability when a patient is referred, transferred, or otherwise is seen by another provider. The origins of the CCR stem from a Massachusetts Department of Public Health, three-page, NCR paper-based Patient Care Referral Form that has been in widespread use over many years in Massachusetts, and from other minimal data sets both electronic and paper-based.

- The CCR is intended to be technology neutral and vendor neutral in order to maximize its applicability. It is being developed on an XML platform in order to offer multiple options for its presentation, modification, and transmittal, e.g., in a browser version, as an HL7® message, in a secure email, as a Word document (electronic or paper). Thus, users will be able to access and view the document in the manner that they prefer and to extract the data as required.

- At this time, the developers are working with the HL7® CDA to design templates for incorporation into the CDA. It considers itself to be a template specification rather than a document specification. It is a very immature standard and remains untested at this date.

ASTM E1384-02 Guide for Content and Structure of the Electronic Health Record (EHR): *Not Selected*

- ASTM E1384-02 is sponsored by ASTM International. ASTM International is one of the largest voluntary standards developing organizations in the world. ASTM is a not-for-profit organization that provides a forum for the development and publication of voluntary consensus standards for materials, products, systems, and services
- The standard guide covers all types of healthcare services, including those given in acute care hospitals, nursing homes, skilled nursing facilities, home healthcare, and specialty care environments as well as ambulatory care. They apply both to short term contacts (for example, emergency rooms and emergency medical service units) and long term contacts (primary care physicians with long term patients). At this time, the standard vocabulary reflects more traditional care. As the standard evolves in the next revisions, the vocabulary will more adequately encompass the entire continuum of care through all delivery models, health status measurement, preventive case, and health education content

The five purposes of the standard are:

1. Identify the content and logical structure of a Electronic Health Record (HER).
2. Define the relationship of data coming from diverse source systems (for example, clinical laboratory information management systems, order entry systems, pharmacy information management systems, dictation systems), and the data stored in the Electronic Health Record. Recalling that the EHR is the primary repository for information from various sources, the structure of the EHR is receptive to the data that flow from other systems.
3. Provides a common vocabulary, perspective, and references for those developing, purchasing, and implementing EHR systems, but it does not deal either with implementation or procurement.
4. Describes examples of a variety of views by which the logical data structure might be accessed/displayed in order to accomplish various functions.
5. Relates the logical structure of the EHR to the essential documentation currently used in the healthcare delivery system within the United States in order to promote consistency and efficient data transfer. It maps to the clinical data currently in existing data systems and patient care records.

Because this standard is has a much broader scope than the HL7® CDA, it can be likened to a framework within which the CDA resides. E1384-02 contains both document standards and non-document standards. CDA addresses only the document portion.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today?

HL7® is used in many places as the messaging standard for Health Care data. Furthermore, HL7® has a great deal of support in the user community and 1999 membership records indicate over 1,600 total members, approximately 739 vendors, 652 healthcare providers, 104 consultants, and 111 general interest/payer agencies. In a survey of 153 chief information officers in 1998, 80% used HL7® within their institutions, and 13.5% were planning to implement HL7® in the future. In hospitals with over 400 beds, more than 95% use HL7®. As an example, one vendor has installed 856 HL7® standard interfaces as of mid 1996. It is the proposed message standard for the Claims Attachment transaction of the Administration Simplification section of the Health Insurance Portability and Accountability Act (HIPAA). Anecdotal information indicates that the major vendors of medical software, including Cerner, Misys (Sunquest), McKesson, Siemens (SMS), Eclipsys, AGFA, Logicare, MRS, Tamtron, IDX (Extend and CareCast), and 3M, support HL7®. The most common use of HL7® is probably admission/discharge/transfer (ADT) interfaces, followed closely by laboratory results, orders, and then pharmacy. HL7® is also used by many federal agencies including VHA, DoD and CDC, hence federal implementation time and cost is minimized. The widespread and long-standing use of HL7® leads to the conclusion that this is a strong recommendation.

What number of or percentage of relevant vendors have adopted the standard?

HL7® has over 2,200 members, which represent over 400 corporate members, including 90 percent of the largest information systems vendors serving healthcare.

Today most major dictation vendors have HL7® CDA capability (MedQuist, Dictaphone and others). Among EHR vendors, Epic, Siemens, GE, McKesson, IDX all have some degree of HL7 CDA capability, although there is a real range among them in terms of sophistication and market-readiness. There is a large number of smaller vendors addressing pieces of the EHR market (ED, rehab, etc) that are also working on CDA solutions.

There are a series of vendors adopting non-healthcare-specific XML tools for CDA; preeminent among them is Microsoft. Adobe is also demonstrating use of their PDF forms generator for CDA. The movement to use desktop tools for healthcare documentation is quite promising in terms of getting useful, reusable electronic data from small providers, who still provide the bulk of care in the US and who have not moved to

adopt complex EHR systems.

Then, there are a large number of vendors with CDA processing applications for storage, retrieval and analysis. This list is extensive and includes, potentially, any vendor with XML capabilities.

What number or percentage of healthcare institutions have adopted the standard?

In the US, a small number of very large institutions have some degree of commitment to a CDA-based document strategy. Mayo is clearly the leader, fully committed to CDA. Less public and less extensive commitments are there from Kaiser, Mayo, the VA, Duke and others. The projects range from full-fledged clinical documentation of all encounters to small, research-oriented pilot projects.

Outside the US, the situation is quite different. There are extensive national HL7 CDA implementations underway in Canada, New Zealand, Japan, Germany, Denmark, Finland and elsewhere.

What number or percentage of federal agencies have adopted the standard?

HL7® is the standard used by all federal government agencies providing healthcare including the Department of Defense, the VA, the Indian Health Service, FDA, CMS and others. HL7® collaborates with government agencies such as the Centers for Disease Control and Prevention (CDC) to provide solutions to public health initiatives in areas such as immunizations, Surveillance, DEEDS, cancer registry, and automated lab reporting.

The Veterans Administration - The VA is reengineering its healthcare applications. The reengineered documentation application will be adopting the HL7® CDA.

Is the standard used in other countries?

HL7® has formal relationships with seven international HL7® affiliate organizations in the following countries: Australia; Canada; Finland; Germany; Japan; New Zealand and The Netherlands. There are extensive national HL7® CDA implementations underway in Canada, New Zealand, Japan, Germany, Denmark, Finland, Greece, the United Kingdom and elsewhere.

CDA:

- PICNIC (European Union)
- SCIPHOX (Germany)
- HYGEIAnet/WebOnColl (Greece)
- Aluetietojärjestelmä (Finland)

- NHS South Staffordshire (United Kingdom)
- MERIT-9 (Japan)
- e-Claims Supporting Document Architecture (Canada)
- Buenos Aires project (Argentina)
- Dalhousie U, QEII Health Sci Ctr (Canada)

Are there other relevant indicators of market acceptance?

The countries that have been most successful in providing ubiquitous access to healthcare information and in making it possible to exchange records outside a single enterprise have done so on the basis of the HL7® CDA. In many cases, they are ahead of the US in the infrastructure for security and confidentiality and this has made is possible to take advantage of CDA for document exchange.

The HL7® CDA is an exchange standard and where documents live in silos, with no potential for reuse or ubiquitous access, there is less incentive for its adoption. The growing interest in a national health information infrastructure here helps build the case for standardizing healthcare documents.

A major impetus to the adoption of CDA has been the proposal for its use in HIPAA Claims Attachments. We are seeing sharply rising indicators of interest from a much wider audience as a result of this proposal.

There is scheduled to be an extensive interoperability demonstration that shows many vendors working with the HL7® CDA and the full family of HL7® specifications at the HIMSS conference in Orlando in February 2004.

Part III – Adoption & Deployment Information

Provide all information gathered in the course of making the recommendation that may assist with adoption of the standard in the federal health care sector. This information will support the work of an implementation team.

Existing Need & Use Environment

Measure the need for this standard and the extent of existing exchange among federal users. Provide information regarding federal departments and agencies use or non-use of this health information in paper or electronic form, summarize their primary reason for using the information, and indicate if they exchange the information internally or externally with other federal or non-federal entities.

Column A: Agency or Department Identity (name)
Column B: Use data in this domain today? (Y or N)
Column C: Is use of data a core mission requirement? (Y or N)
Column D: Exchange with others in federal sector now? (Y or N)
Column E: Currently exchange paper or electronic (P, E, B (both), N/Ap)
Column F: Name of paper/electronic vocabulary, if any (name)
Column G: Basis/purposes for data use (research, patient care, benefits)

Department/Agency	B	C	D	E	F	G
Department of Veterans Affairs	Y	Y	Y	B	HL7® RIM, ICD, CPT®, LOINC®	research, patient care, benefits
Department of Defense	Y	Y	Y	B	HL7® RIM, ICD, CPT®, LOINC®	research, patient care, benefits
HHS Office of the Secretary	Y		Y	B	ICD, CPT®	research, benefits
Administration for Children and Families (ACF)	Y	Y	Y	B	ICD, CPT®	research, patient care, benefits
Administration on Aging (AOA)	Y	Y	Y	B	ICD, CPT®	research, patient care, benefits
Agency for Healthcare Research and Quality (AHRQ)	Y	Y	Y	B	ICD, CPT®	research, patient care, benefits
Agency for Toxic Substances and Disease Registry (ATSDR)	Y	Y	Y	B	ICD, CPT®	research, patient care, benefits
Centers for Disease Control and Prevention (CDC)	Y	Y	Y	B	HL7® RIM, ICD, CPT®, LOINC®	research, patient care, benefits

Centers for Medicare and Medicaid Services (CMS)	Y	Y	Y	B	HL7® RIM, ICD, CP®T, LOINC®	research, patient care, benefits
Food and Drug Administration (FDA)	Y	Y	Y	B	ICD, CPT®, LOINC®?	research, patient care, benefits
Health Resources and Services Administration (HRSA)	Y	Y	Y	B	ICD, CPT®,	research, patient care, benefits
Indian Health Service (IHS)	Y	Y	Y	B	HL7® RIM, ICD, CPT®, LOINC®	research, patient care, benefits
National Institutes of Health (NIH)	Y	Y	Y	B	ICD, CPT®, LOINC®	research, patient care, benefits
Substance Abuse and Mental Health Services Administration (SAMHSA)	Y	Y	Y	B	ICD, CPT®	research, patient care, benefits
Social Security Administration	Y	Y	Y	B		benefits
Department of Agriculture	Y					research
State Department		N	Y			research
US Agency for International Development	Y	Y	Y	B		research, patient care
Justice Department	Y	Y	Y	B	ICD, CPT®,	research, patient care, benefits
Treasury Department	N	N	N	N/Ap		
Department of Education						
General Services Administration	Y	Y	N	B	ICD, CPT®, LOINC®	System deployment
Environmental Protection Agency	Y	Y	Y	B	ICD, CPT®	research, patient care
Department of Housing & Urban Development						
Department of Transportation						
Homeland Security	Y	Y	Y	B	ICD, CPT®	research, patient care, benefits

Number of Terms

Quantify the number of vocabulary terms, range of terms or other order of magnitude.

CDA draws its vocabulary from the HL7® Reference Information Model (RIM). The RIM has internal HL7® vocabulary tables but to the greatest extent possible relies on externally maintained standard vocabularies, such as LOINC®, ICD, SNOMED®, etc.

How often are terms updated?

The HL7® RIM is revised three times per year, but the external vocabularies [LOINC®, ICD, SNOMED®, etc] each have their own cycle.

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)

The RIM has internal HL7® vocabulary tables that are complete and functioning, but to the greatest extent possible relies on externally maintained standard vocabularies, such as LOINC®, ICD, SNOMED®, etc. that are complete, supported and in general use today.

Acquisition: *How are the data sets/codes acquired and use licensed?*

Standards are available from HL7®. HL7® asserts and retains copyright in all works contributed by members and non-members relating to all versions of the Health Level Seven standards and related materials, unless other arrangements are specifically agreed upon in writing. No use restrictions are applied.

However some of the externally maintained standard vocabularies contained in the HL7® RIM, such as LOINC®, ICD, SNOMED®, etc. require licensing fees. Of note, on July 1, 2003, Secretary Thompson announced that the Department of Health and Human Services (DHHS) entered into a licensing agreement to make a clinical terminology database, SNOMED®, available without charge to the U.S. health care industry.

Cost

What is the direct cost to obtain permission to use the data sets/codes? (licensure, acquisition, other external data sets required, training and education, updates and maintenance, etc.)

HL7® sells hard and computer readable forms of the various standard versions, cost from $50 - $500 depending on specific standard and member status. Draft versions of standards are available to all from their website. No specific cost is associated with using the standards.

Training is offered through HL7® and others are varying costs from several hundred to several thousand-dollars/per person. Consultation services are available at standard industry cost for training, update instillation and maintenance.

Systems Requirements

Is the standard associated with or limited to a specific hardware or software technology or other protocol?

No, it is platform independent.

Guidance

What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?

HL7® is in widespread use and has many implementation guides and tools, some in the public domain and some accessible by authorized personnel or organizations. Please refer to www.hl7.org for more details.

Is a conformance standard specified? Are conformance tools available?

A standard is not specified. Conformance tools are not available through the SDO, but private sector tools do exist.

Maintenance

How do you coordinate inclusion and maintenance with the standards developer/owners?

Voluntary upgrade to new versions of standards, generally by trading partner agreement. Messages are transmitted with version number and use of prior versions is generally supported for a period of time after introduction of a new one.

What is the process for adding new capabilities or fixes?

Continual review of in-use requirements of standard at organization meetings held three times/year.

What is the average time between versions?

Various, but approximately annually.

What methods or tools are used to expedite the standards development cycle?

None. Occurs at meetings held three times/year and in the workgroups between meetings. Standards development can be quite lengthy.

How are local extensions, beyond the scope of the standard, supported if at all?

Yes, but not encouraged. XML is an extensible language allowing for local variation and extension; however, the document must conform with a CDA DTD or Schema in order to be exchanged.

Customization

Describe known implementations that have been achieved without user customization, if any.

Not known if any implementations have been achieved without user customization, however, see discussion below.

If user customization is needed or desirable, how is this achieved? (e.g, optional fields, interface engines, etc.)

The way to understand this question and the one above in terms of CDA is to look at implementations that add constraints on top of the CDA, which is generic to all / any healthcare documents. The Claims Attachments proposal is an example of the degree of variability in customization -- where broad utilization is desirable, with minimal requirements, the "Human Decision Variant" which is highly transportable and easily generated requires little customization. The "Computer Decision Variant" sets the bar for interoperability quite a bit higher, is more difficult to generate and provides greater re-use value to recipients.

Different implementations have taken different positions on the degree of customization required. This is anticipated in the design of CDA -- it is a fundamental design principle that users have this range of choice:

- Little customization would yield ease of generation, widespread application for

access to human-readable, platform independent information.

- High customization requires tighter conformance requirements, greater application for automated decision support and insertion into registries and for public health reporting.

Mapping Requirements

Describe the extent to which user agencies will likely need to perform mapping from internal codes to this standard.

Anticipate that it should not be extensive, the HL7® CDA uses the HL7® V3 data types and can support both local codes and standard vocabulary, although in some few instances, local codes are not allowed.

Identify the tools available to user agencies to automate or otherwise simplify mapping from existing codes to this standard.

A variety of tools are available and are dependant on what terminology needs to be mapped.

Compatibility

Identify the extent of off-the-shelf conformity with other standards and requirements:

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception
NEDSS requirements	**X**		
HIPAA standards	**X**		
HL7® 2.x	**X**		

Implementation Timeframe

Estimate the number of months required to deploy this standard; identify unique considerations that will impact deployment schedules.

CDA, Release One is already an ANSI standard, already deployed in a number of places. CDA, Release Two will likely require one if not two more ballot cycles, it is anticipated that it will become a standard around mid to late 2004. There are a number of early adopters prototyping CDA, Release Two now, and it will be featured as part of the HL7® HIMSS Interoperability Demo in 2004.

Too many institution specific considerations come into play in determining how long the deployment of a CDA standard would.

If some data sets/code sets are under development, what are the projected dates of completion/deployment?

CDA doesn't require any specific data sets/code sets. It's a general XML-based representation of a clinical document, to which templates or specific constraints can be applied. For instance, HL7® has balloted a recommendation for using CDA for Claims Attachments, which lays out specific requirements for LOINC® codes. Where CDA allows for any number of codes, the specific implementation guide constrains the set to specific LOINC® codes. Based on that it is anticipated that data sets, code sets, and templates will be in a state of continuous evolution and consensus building over the next few years.

Gaps

Identify the gaps in data, vocabulary or interoperability.

The CDA doesn't require specific terminologies for diagnoses, procedures, etc - so in that regard, the standard can evolve in parallel to the evolution of standard terminologies. A particular implementation can choose to only allow for specific section codes, observation codes, etc. So the main gaps are those found in the specific terminologies used. These don't impact the deployment of CDA, but CDA will benefit from cleaner and more comprehensive terminologies.

Obstacles

What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)

CDA, Release One is a relatively simple standard, with fielded data in the document header, and a document body that is close to HTML (with a little more structure) - the technical and financial barriers are intentionally very low. It is roughly following a fairly natural penetration of a new standard, where vendors have been cautious in their adoption, waiting to see that customers will want it.

CDA, Release Two has a richer structured body, allowing for detailed semantic representation. However, the rich structuring is optional, so technical and financial barriers can be low. For instance, there have been a number of forms-based and Natural Language Processing-based interfaces being able to populate CDA, Release Two.

A complete understanding of the model of the CDA document body does require a certain level of technical expertise, involving an understanding of XML, the HL7® Reference Information Model (RIM), and the HL7® Version 3 data types. So for those wanting to fully exploit CDA, Release Two, there are technical hurdles mainly involved in gaining a full understanding - analogous to the hurdles faced by those implementing

HL7® Version 3 messages.

Financial implications will also depend on the extent to which vendors choose to fully encode the narrative in a clinical document. This encoding can require mapping legacy databases against the RIM. In addition, the ability to take advantage of the richness may require that an application's data store be enhanced.

Appendix A

Information Exchange Requirements (IERs)

Information Exchange Requirement	Description of IER
Beneficiary Financial / Demographic Data	Beneficiary financial and demographic data used to support enrollment and eligibility into a Health Insurance Program.
Beneficiary Inquiry Information	Information relating to the inquiries made by beneficiaries as they relate to their interaction with the health organization.
Beneficiary Tracking Information	Information relating to the physical movement or potential movement of patients, beneficiaries, or active duty personnel due to changes in level of care or deployment, etc.
Body of Health Services Knowledge	Federal, state, professional association, or local policies and guidance regarding health services or any other health care information accessible to health care providers through research, journals, medical texts, on-line health care data bases, consultations, and provider expertise. This may include: (1) utilization management standards that monitor health care services and resources used in the delivery of health care to a customer; (2) case management guidelines; (3) clinical protocols based on forensic requirements; (4) clinical pathway guidelines; (5) uniform patient placement criteria, which are used to determine the level of risk for a customer and the level of mental disorders (6) standards set by health care oversight bodies such as the Joint Commission for Accreditation of Health Care Organizations (JCAHO) and Health Plan Employer Data and Information Set (HEDIS); (7) credentialing criteria; (8) privacy act standards; (9) Freedom of Information Act guidelines; and (10) the estimated time needed to perform health care procedures and services.
Care Management Information	Specific clinical information used to record and identify the stratification of Beneficiaries as they are assigned to varying levels of care.
Case Management Information	Specific clinical information used to record and manage the occurrences of high-risk level assignments of patients in the health delivery organization..
Clinical Guidelines	Treatment, screening, and clinical management guidelines used by clinicians in the decision-making processes for providing care and treatment of the beneficiary/patient.

Cost Accounting Information	All clinical and financial data collected for use in the calculation and assignment of costs in the health organization.
Customer Approved Care Plan	The plan of care (or set of intervention options) mutually selected by the provider and the customer (or responsible person).
Customer Demographic Data	Facts about the beneficiary population such as address, phone number, occupation, sex, age, race, mother's maiden name and SSN, father's name, and unit to which Service members are assigned
Customer Health Care Information	All information about customer health data, customer care information, and customer demographic data, and customer insurance information. Selected information is provided to both external and internal customers contingent upon confidentiality restrictions. Information provided includes immunization certifications and reports, birth information, and customer medical and dental readiness status
Customer Risk Factors	Factors in the environment or chemical, psychological, physiological, or genetic elements thought to predispose an individual to the development of a disease or injury. Includes occupational and lifestyle risk factors and risk of acquiring a disease due to travel to certain regions.
Encounter (Administrative) Data	Administrative and Financial data that is collected on patients as they move through the healthcare continuum. This information is largely used for administrative and financial activities such as reporting and billing.
Improvement Strategy	Approach for advancing or changing for the better the business rules or business functions of the health organization. Includes strategies for improving health organization employee performance (including training requirements), utilization management, workplace safety, and customer satisfaction.
Labor Productivity Information	Financial and clinical (acuity, etc.) data used to calculate and measure labor productivity of the workforce supporting the health organization.
health organization Direction	Goals, objectives, strategies, policies, plans, programs, and projects that control and direct health organization business function, including (1) direction derived from DoD policy and guidance and laws and regulations; and (2) health promotion programs.
Patient Satisfaction Information	Survey data gathered from beneficiaries that receive services from providers that the health organization wishes to use to measure satisfaction.

Patient Schedule	Scheduled procedure type, location, and date of service information related to scheduled interactions with the patient.
Population Member Health Data	Facts about the current and historical health conditions of the members of an organization. (Individuals' health data are grouped by the employing organization, with the expectation that the organization's operations pose similar health risks to all the organization's members.)
Population Risk Reduction Plan	Sets of actions proposed to an organization commander for his/her selection to reduce the effect of health risks on the organization's mission effectiveness and member health status. The proposed actions include: (1) resources required to carry out the actions, (2) expected mission impact, and (3) member's health status with and without the actions.
Provider Demographics	Specific demographic information relating to both internal and external providers associated with the health organization including location, credentialing, services, ratings, etc.
Provider Metrics	Key indicators that are used to measure performance of providers (internal and external) associated with the health organization.
Referral Information	Specific clinical and financial information necessary to refer beneficiaries to the appropriate services and level of care.
Resource Availability	The accessibility of all people, equipment, supplies, facilities, and automated systems needed to execute business activities.
Tailored Education Information	Approved TRICARE program education information / materials customized for distribution to existing beneficiaries to provide information on their selected health plan. Can also include risk factors, diseases, individual health care instructions, and driving instructions.